Deleted claims

Please delete claim 31

Add the following claims

34. The process of claim 27 wherein the carboxyl functional polymer is poly(acrylic acid), the biomedical device is a contact lens, and the coupling agent is 1-ethyl-3-(3-dimethylaminopropyl)carbodiimide.

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35. The process of claim 28 wherein the carboxyl functional polymer is poly(acrylic acid), poly(methacrylic acid), poly(maleic acid), poly(itaconic acid), block or random copolymer of methacrylic acid or acrylic acid, acrylic acid, maleic acid or itaconic acid with a reactive vinyl monomer.

36. The process of claim 28 wherein the carboxyl functional polymer is poly(acrylic acid).

37. The process of claim 28 wherein the coupling agent is 1-ethyl-3-(3-dimethylaminoporpyl)carbodiimide.

REMARKS

Upon entry of the proposed amendments seven (7) claims are pending in this application. The amendment to claims 27, 29, 30, and 33 do not add new matter to the application. The additional claims 34-37 do not add new matter to the application. Support for these claims may be found in claims 1, 27-33 as originally filed.

In the Office Action

> Claims 27-33 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over Winn '009 or Kamel '924 or Fan '205 or Sahatjian '516 or Murayama '211 or Opolski '012 or Shimaura '488 or Fan '899 or Fan '738 or Onishi '588 or Whitbourne'517. Applicants' claims are directed to a process for coating a "device" comprising contacting the surface with a carboxy polymer and a coupling agent. All of these references disclose or suggest applying compositions of carboxyl polymer and materials which qualify as coupling agent to the surface of devices. See the Abstract and claim 1 of each of these references. It would be obvious to one of ordinary skill in the art to apply a composition of carboxyl polymer and a material in these references which qualifies as coupling agent to the surface of a device. The motivation is that the use of polymer together with material which qualifies as coupling agent is suggested by these references.

Applicants respectfully traverse this rejection for the following reasons.

As amended Applicants claim process for producing a biomedical device using certain coupling agents. None of those coupling agents are suggested by the cited references. In addition, Applicants' claimed coupling agents chemically interact with the carboxyl functional polymer surface of the biomedical device in a manner that is not suggested by the references. A summary of each of the references and the features that distinguish Applicants invention from each of these references is presented below.

Winn discloses a method of coating the surface of a biomedical substrate comprising first coating said substrate with a polyisocyanate to give a coating having unreacted isocyanates . Subsequently the isocyanate coated device is reacted with a hydrophilic copolymer to form a covalent bond between the isocyanate coupling agent and the active hydrogen of the hydrophilic copolymer. (Winn, claim 1) Winn is distinguishable from Applicants claimed invention in two aspects. First, Winn teaches coupling agents that are incorporated into the final coated articles. Applicants coupling agents facilitate (alternatively catalyze) the coupling between the hydroxyl or amino group of the biomedical device and the carboxyl group of hydrophilic polymer, but are not incorporated into the final coated articles. Second, Winn requires two coating steps to produce the coated article, adding the isocyanate coating, then subsequently reacting said isocyanate coated article

with another coating. Applicants claimed process only uses one coating step. Therefore, Applicants claimed process is not suggested by Winn.

Whitbourne discloses a biomedical device having a first layer that is bonded to the device and a second layer that is strongly bonded to the first layer, where the surface of the device does not contain reactive functional groups. (Whitborne, col. 3, lines 37-47). This invention may be distinguished from Applicants invention in two aspects. First Applicants invention requires biomedical devices containing reactive functional groups, namely hydroxyl groups, amino groups or mixtures thereof. Whitborne, explicitly teaches away from this requirement. Second, Applicants' invention comprising one coating layer and Whitborne requires two. Therefore Applicants claimed process is not suggested by Whitbourne.

Onishi discloses process for producing a biomedical device that is coated with a water-soluble or water-swellable polymer having a reactive functional group selected from the group consisting of epoxy group, acid chloride group, aldehyde group, and isocyanate group. (Onishi, col. 2, lines 29-36) Applicants' invention can be distinguished from Onishi in two ways. First, Applicants' process requires coatings that contain reactive carboxyl groups. These groups are not suggested by Onishi. Second, Applicants' processes require that at least one surface of the biomedical device contain hydroxyl groups, amino groups or mixtures thereof. Onishi does not suggest that the surface of the biomedical devices contain any reactive functionality, particularly hydroxyl or amino groups.

Fan '738 discloses processes for coated devices where the coating comprises at least two polymers, a binding polymer and a lubricious coating polymer. (Fan '738, claim 1) In addition, Fan '738 discloses that the substrates to be coated are selected from the group consisting of polyurethane, polyvinyl chloride, and the like. (Fan '738, claim 2). Applicants' processes require substrates containing reactive functional groups that are not suggested by Fan '738. In addition, Applicants' processes do not require the use of the binder polymers of Fan '738. Therefore Applicants' claimed invention is distinguishable over Fan '738.

Fan '899 discloses a medical device with two distinct coatings, one a hydrophilic coating and the other a lubricious blood-compatible second

coating. (Fan '899, claim 1). Applicants' processes require substrates containing reactive functional groups that are not suggested by Fan '899. In addition, Applicants' process require particular coupling groups that are not suggested by Fan '899. Still further Fan '899 requires two separate coating steps to produce the claimed articles and Applicants' claimed processes require only one step. Therefore Applicants' claimed invention is distinguishable over Fan '899.

Shimura discloses a medical tool which is comprises a water-swellable polymer containing a reactive functional group in the molecular unit thereof and a matric material capable of reacting with the reactive functional group. (Shimura, col. 2, lines 25 to 28). The reactive functional groups of the water swellable polymer are epoxy groups, acid halide groups and isocyanate groups. (Shimura, col 2, lines 33-36) The carboxyl functional polymers of Applicants' invention are neither taught nor suggested by Shimura. In addition, the coupling agents of Applicants' claimed processes are neither taught or suggested by Shimura. Therefore Applicants' claimed invention is distinguishable over Shimura.

Opolski discloses methods for providing a medical apparatus where said method comprises "applying a coating solution to a surface of the medical apparatus ... wherein the coating solution comprises a protective compound and a slip additive and the formed layer contains the protective compound as a binder to maintain domains of the slip additive such that lubricating amounts of the slip additive are exposed to provide lubricity." (Opolski, claim 1). Opolski's coating requires two components where the slip additive may be hydrophilic or hydrophobic in nature, and the protective compound is capable of protecting the surface of the medical apparatus. (Opolski, col. 2, lines 44-45; col. 2, lines 12-13, respectively). The carboxyl functional hydrophilic polymer that are used in Applicants' processes are not suggested by Opolski. In addition, Applicants do not require a protective compound. Still further, the surface of Applicants' devices must posses hydroxyl or amino groups. Opolski's medical apparatus do not require the presence of such groups. Therefore, Applicants' claimed processes are distinguishable over Opolski.

Fan 205' discloses methods of coating a substrate with a hydrophilic coating where the methods comprises two steps "(1) contacting said substrate with polyisocyanate contained in at least one first inert solvent to provide at least a partially coated substrate; contacting said coated substrate with a poly (acrylic acid) polymer ...." Fan 205 is distinguishable from Applicants' claimed process because it requires two separate steps. In addition, Applicants' process requires hydroxyl groups or amino groups on the surface of medical device and these groups are not suggested by Fan '205. Further, Fan '205 incorporates isocyanates into the surface of its medical devices and in turn couples those isocyanates to a poly (acrylic acid) polymer. The coupling agents of Applicants' invention are not incorporated into the resulting coated device and these coupling agents are not suggested by Fan '205.

Sahatjian discloses "methods of rendering a surface of a preformed article lubricious and antithrombogenic comprising providing on said surface a thin coating of biologically compatible, lubricious hydrophilic polymer including acid groups and thereafter applying to said coating ammonium cation, heparin and buffer solution ... ." (Sahatjian, claim 1). Applicants claimed processes are distinguishable over Sahatjian for the following reasons. The hydroxyl or amino groups that are required by Applicants' invention are not suggested by Sahatjian. In addition, the articles of Sahatjian are coated with isocyanates and dried prior to treatment with polyacrylic acid and the coupling agents of Applicants' invention are not suggested by Sahatjian. (Sahatjian, col. 7, examples 1 and 2). Therefore, the one step process of Applicants' invention is not suggested by Sahtjian.

Murayama discloses coating devices with hydrophilic polymers. This patent discloses the use of isocyanate to attach to the surface of the device and to use resulting isocyanate prepolymers to attach hydrophilic polymers to the surface of the device. (Murayama, col. 9, example 1). In this manner, the coupling agents are incorporated into the final coated device. Applicants' invention is distinguishable from Murayama because the coupling agents of Applicants' methods are not incorporated into the final device. In addition, there is no teaching in Murayama of using the coupling agents of Applicants' invention.

Kamel discloses grafting a first biomedical material having pendant terminal carboxylic acid or amine groups to the surface of a substrate by radio frequency plasma induction. (Kamel, col. 4, lines 55-59). Applicants' claimed method, namely using a coupling agent, is not suggested by this patent, therefore Applicants' invention is distinguishable over this patent.

As discussed individually above none of the cited references teaches the coupling agents of Applicants' claimed invention. For those references that generically disclose coupling agents, they disclose agents that become incorporated into the final device because they essentially link the hydrophilic polymer to the uncoated surface of the device. In addition, none of the references require that the uncoated surface of the device contain hydroxyl groups, amino groups or mixtures thereof, as is required by Applicants' invention. Therefore, Applicants' claim invention would not be obvious to one of ordinary skill in the art in light of the cited references.

In the Office Action,

> claims 27-33 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over Hammond '672, Dollan '596, or Yamasoe '359, or Gregor '873 or Nadkarni '035 or Jones '107 or Kramer '436. All of these references disclose the application of carboxyl polymers and material which qualify as "coupling agent" to the surface of devices. Applicants do not define "biomedical device" either in the specification or the claims. Any article can theoretically be used in a biomedical situation and thereby considered to be a "biomedical device." Therefore, the Examiner is taking the position that all of the devices or substrated show by these reference qualify as "biomedical device." It would be obvious to one of ordinary skill in the art to apply a composition comprising carboxyl polymer and a material which qualifies as "coupling agent to the disclosed devices or substrates show by these references.

Applicants traverse this rejection for the following reasons.

Hammond discloses coating optical materials with a mixture of polyacrylic acid and hexamethoxymelamine. (Hammond, col. 3-4, examples 1 and 2) This process requires heating and does not use a coupling agent. In addition, there is no requirement that the surface optical materials of Hammond contain hydroxyl groups, amine groups or mixtures thereof. Therefore Applicants' claimed invention is distinguishable over Hammond.

Dollman discloses an acidic solution for coating the surface of a metal with polyacrylic acid. (Dollman, claim 1). Dollman neither uses coupling agents of Applicants' claimed invention or requires that the metal surfaces possess hydroxyl groups, amino groups, or mixtures thereof. Therefore Applicants' claimed invention is distinguishable over Dollman.

Nadkarni discloses a composition for coating the surface of a metal with polyacrylic acid. (Nadkarni, claim 1). Nadkarni neither uses coupling agents of Applicants' claimed invention or requires that the metal surfaces possess hydroxyl groups, amino groups, or mixtures thereof. Therefore Applicants' claimed invention is distinguishable over Nadkarni.

Yamasoe discloses coating the surface of a metal with carboxycellulose and N-methylolacrylamide. (Yamasoe, claim 1). Yamasoe neither uses coupling agents of Applicants' claimed invention or requires that the metal surfaces possess hydroxyl groups, amino groups, or mixtures thereof. Therefore Applicants' claimed invention is distinguishable over Yamasoe.

Kramer discloses coating derived from polyacrylic acid and other components that may be used to coat metals. (Kramer, claim 1) Kramer neither uses coupling agents of Applicants' claimed invention or requires that the metal surfaces possess hydroxyl groups, amino groups, or mixtures thereof. Therefore Applicants' claimed invention is distinguishable over Kramer.

Jones discloses a composition for treating metal surfaces to improve paint adhesion and corrosion resistance comprising two polymers. Jones neither uses coupling agents of Applicants' claimed invention or requires that the metal surfaces possess hydroxyl groups, amino groups, or mixtures thereof. Therefore Applicants' claimed invention is distinguishable over Jones.

Gregor discloses a process for converting hydrophobic nitrile groups to pendant amide groups (Gregor, claim 1). Gregor neither uses coupling agents of Applicants' claimed invention or requires that the surfaces to be coated possess hydroxyl groups, amino groups, or mixtures thereof. Therefore Applicants' claimed invention is distinguishable over Gregor.

As discussed individually above none of the cited references teaches the coupling agents or the surfaces of Applicants' claimed invention. Therefore, the claimed invention would not be obvious to one of ordinary skill in the art in view of these references. Applicants respectfully submit that the rejection of claims 27-33 under 35 U.S.C. 103 (a) in view of these references has been overcome and should be withdrawn.

Further Applicants respectfully traverse the assertion that ""biomedical device" is not defined in the specification. The term is defined in the specification (pg. 2, lines 7-12). A particular biomedical device, an opthalmic lens, is exemplified by the preparation and examples in the specification. (pgs. 12-17). Applicants respectfully request that the PTO withdraw this assertion.

In light of the foregoing, amendments and reasoning Applicants respectfully assert that all claims are in condition for allowance. A notice of allowance of all claims is respectfully solicited. A marked version of the amended claims follows where deletions are noted by a strike through (~~text~~) and additions are underlined (text). If the Examiner believes an interview would expedite the disposition of this patent application, the Examiner is invited to call the undersigned agent collect at (732) 524-1024.

Respectfully submitted,

Ruby T. Hope
Reg. No. 34,350
Attorney for Applicants

Johnson & Johnson
One Johnson and Johnson Plaza
New Brunswick, New Jersey 08933
(732)524-1024
Dated: October 2, 2001

VERSION WITH MARKINGS TO SHOW CHANGES MADE TO AMENDED SPECIFICATION AND CLAIMS

The following amendments were made to the claims

27. (Once amended) A process for manufacturing biomedical devices, wherein at least one surface of said device comprises hydroxyl groups, amino groups, or mixtures thereof,

wherein the process comprises the step of contacting at least one surface of a biomedical device with a coating effective amount of at least one carboxyl functional hydrophilic polymer and a coupling effective amount of at least one coupling agent, wherein the coupling agent is selected from the group consisting of carbodiimides, N,N'-carbonyldiimidazole, phosphoryl chloride, titanium tetrachloride, sulfuryl chloride fluoride, chlorosulfonyl isocyanate, phosphorus iodide, pyridinium salts of tributyl amine, phenyl dichlorophosphate, polyphosphate ester, chlorosilanes, a mixture of tributyl phosphorous and phenyl isocyanate, a mixture of alkyl chloroformates and triethyl amine, a mixture of 2-chloro-1,3,5-trinitrobenzene and pyridine, a mixture of methyl sulfuryl chloride and diethyl amine, and a mixture of triphenylphosphine, carbon tetrachloride and triethylamine.

29. (Once amended) The ~~device~~ process of claim 27 wherein the carboxyl functional polymer is poly(acrylic acid), poly(methacrylic acid), poly(maleic acid), poly(itaconic acid), block or random copolymer of methacrylic acid or acrylic acid, acrylic acid, maleic acid or itaconic acid with a reactive vinyl monomer.

30. (Once amended) The ~~device~~ process of claim 27 wherein the carboxyl functional polymer is poly(acrylic acid).

33. (Once amended) The process of claim 27 wherein the ~~carbodiimide~~ coupling agent is 1-ethyl-3-(3-dimethylaminoporpyl)carbodiimide.